

19. (Amended) A pharmaceutical composition comprising as the active agent, a monoclonal autoantibody selected from the group consisting of monoclonal autoantibody capable of inducing remyelination of central nervous system axons and synthetic autoantibody capable of inducing remyelination of central nervous system axons.

Please add the following claims:

Rule 126 22°
24. A pharmaceutical composition comprising as the active agent, a monoclonal autoantibody selected from the group consisting of an antigen binding fragment of SCH 79.08.

REMARKS

The foregoing amendments and the following remarks are submitted in response to the communication dated May 29, 2002.

Status of the Claims

Claims 1-4, 9-14, and 19-21 are pending in the application. Claims 19 has been amended and new Claim 24 is presented in order to more particularly point out and distinctly claim that which Applicants regard as the invention. Support for the amended and new claims can be found generally through Applicants' Specification.

The Specification Fully Enables the Claimed Invention

The Examiner has rejected claims 1-4, 9-14 and 19 under 35 U.S.C. 112, first paragraph,

because the Examiner asserts that the Specification, while being enabling for methods of stimulating remyelination or treating demyelinating disease in a mammal by administering an effective amount of monoclonal antibodies that induce remyelination of central nervous system axons, the specific monoclonal autoantibodies: A2B5, SCH79.08 and synthetic monoclonal autoantibodies, monoclonal autoantibodies 01, 04, and HNK-1 are not enabled. Applicants recognize and appreciate the Examiners concurrence that the new claims as presented in Applicants' previous response and "drawn to monoclonal autoantibodies or monoclonal autoantibodies that are synthetic and that induce remyelination of central nervous system axons are enabled". Thus, with respect to the antibodies 01, 04 and HNK-1, the only remaining issue is the public availability of the specific antibody clones. The Examiner remarks that Applicants' evidence of the public availability for sale of HNK-1 provided in Applicant's response of November 7, 2001 was inadvertently not attached and provided with the response. Applicants provide herewith as attached Exhibit I a further copy of the evidence of earlier Exhibit I, specifically demonstrating that, in addition to Becton Dickinson and Lab Vision Corporation, as earlier provided, the ATCC offers the HNK-1 clone for sale. Applicants submit that the HNK-1 antibody is publicly available and is, in fact, offered for sale by several sources.

Applicants again argue and assert that the O1 and O4 antibodies are publicly available and for sale. Applicants once again point to the clear evidence presented in prior responses. Specifically, Applicants have demonstrated that the O1 and O4 antibodies have been offered for sale by Roche Molecular Biochemicals, USA and are presently being distributed by Chemicon International. The sales material and technical data sheets of Chemicon clearly refer back to the Roche distributed antibodies and further clearly and solely reference the isolation of tehse O1 and

O4 antibodies by the laboratory of Dr. Melitta Schachner, as also referenced by Applicants in the Specification. Applicants have further provided a declaration of Dr. Moses Rodriguez stating and establishing that the O1 and O4 antibodies offered for sale by Roche Molecular Biochemicals USA (now distributed by Chemicon International as noted) are the same as the O1 and O4 antibodies provided and claimed in the instant Application. Applicants submit that the O1 and O4 antibodies are publicly available and are, in fact, offered for sale by commercial sources. Applicants appeal to the Examiner to withdraw this rejection in view of the clear evidence provided.

In view of the foregoing remarks, Applicants submit that the Examiner's rejection under 35 U.S.C. 112, first paragraph, may properly be withdrawn.

The 35 U.S.C. 102 Rejections

The Examiner has rejected Claim 19 under 35 U.S.C. 102(b) as anticipated by Abo et al. (J. Immunol., 127:1024-1029, 1981) or American Type Culture Collection Catalog, 1992, page 435, which the Examiner asserts teach the monoclonal antibody HNK-1 and anticipate the product claim. The Examiner remarks that HNK-1 broadly reads on Claim 19 as it recites monoclonal synthetic autoantibodies. Applicants respectfully disagree and submit that in as much as applicants specification teaches that monoclonal antibody HNK-1 is an autoantibody and further teaches its use in the methods including remyelination of the instant application, Abo et al. and the ATCC catalog do not anticipate the product claim. Applicants respectfully request the Examiners rejection under 35 U.S.C. 102(b) be withdrawn.



CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,
KLAUBER & JACKSON

A handwritten signature in cursive script, reading "David A. Jackson".

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

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IN THE CLAIMS:

19. (Amended) A pharmaceutical composition comprising as the active agent, a monoclonal autoantibody selected from the group consisting of [an antigen binding fragment of SCH 79.08,] monoclonal autoantibody capable of inducing remyelination of central nervous system axons and synthetic autoantibody capable of inducing remyelination of central nervous system axons.
24. (New) A pharmaceutical composition comprising as the active agent, a monoclonal autoantibody selected from the group consisting of an antigen binding fragment of SCH 79.08.